IMPACT OF FAST-TRACK REHABILITATION PROTOCOL FOLLOWING PANCREATICODUODENECTOMY

Dissertation Submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfillment of the regulations

For the award of the degree of

M.CH (SURGICAL GASTROENTEROLOGY & PROCTOLOGY)

BRANCH – VI

INSTITUTE OF SURGICAL GASTROENTEROLOGY & LIVER TRANSPLANTATION

GOVT. STANLEY MEDICAL COLLEGE & HOSPITAL,

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

CHENNAI, INDIA.

AUGUST 2013

CERTIFICATE

This is to certify that the dissertation entitled **"IMPACT OF FAST-TRACK REHABILITATION PROTOCOL FOLLOWING PANCREATICO-DUODENECTOMY"** is the bonafide original work of **Dr. A. SASTHA** in partial fulfillment of the requirement for **M.CH. (Branch VI) Surgical Gastroenterology & Proctology** examination of The Tamilnadu Dr. M.G.R. Medical University to be held in August 2013. The period of study is from April 2012 to December 2012.

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DECLARATION

I, Dr**. A. SASTHA**, solemnly declare that the dissertation titled, **"IMPACT OF FAST-TRACK REHABILITATION PROTOCOL FOLLOWING PANCREATICODUODENECTOMY**" is a bonafide work done by me at Govt. Stanley Medical College during 20010 - 2013 under the guidance and supervision of **Prof. G. MANOHARAN M.S., M.CH**, Professor and Head, Institute of Surgical Gastroenterology & Liver Transplantation, Stanley Medical College, Chennai – 600 001.

The dissertation is submitted to **The Tamilnadu, Dr. M.G.R. Medical University**, towards partial fulfillment of requirement for the award of **M.CH Degree (BRANCH – VI) in Surgical Gastroenterology & Proctology.**

Place: Chennai.

Date: March 2013 **(Dr. A. SASTHA)**

ACKNOWLEDGEMENTS

I would like to express my profound gratitude to **Dr. S. GEETHALAKSHMI, M.D., PHD,** Dean, Government Stanley Medical College and Hospital, Chennai for permitting me to use all the needed resources for this dissertation work.

I sincerely express my grateful thanks to **Prof. G. MANOHARAN, M.S., M.CH,** Professor and Head, Institute of Surgical Gastroenterology & liver transplantation, Stanley Medical College, **Prof. P.RAVICHANDRAN, M.S, M.CH**, Professor, Institute of Surgical Gastroenterology & liver transplantation, Stanley Medical College and **Prof. S. JESWANTH, M.S, M.CH**, Professor, Institute of Surgical Gastroenterology & liver transplantation, Stanley Medical College for their unstinted support and advice rendered throughout my study. I thank them for being a constant source of encouragement, inspiration, not only in this study but in all my professional endeavors.

I express my sincere thanks to my Assistant Professors, **Dr. R. Ravi, Dr. P. Senthilkumar, Dr. U. P. Srinivasan, Dr. R. Sukumar and Dr. R. Kamala kannan,** for their unstinted encouragement, guidance and valuable suggestions throughout the period of study.

I also sincerely thank the Ethical Committee, SMC, Chennai for approving my study.

I extend my sincere thanks to my subjects but for them the project would not have been possible.

I am greatly indebted to all my friends, postgraduate colleagues who have been the greatest source of encouragement, support, enthusiasms, criticism, friendly concern and timely help.

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Title of the Work : Impact of fast track rehabilitation protocol following Pancreaticododenectomy

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INTRODUCTION

INTRODUCTION

Malignancies of the head of pancreas and the periampullary region are managed surgically by pancreaticoduodenectomy (PD). Few decades back PD was associated with a very high morbidity and mortality. Recent advancements in surgical and anaesthetic techniques and the improvement in peri-operative care have evolved PD into a procedure with acceptable morbidity and mortality. Today PD is associated with a mortality of less than 5% in high volume tertiary care centres[1 – 7]. But the morbidity rate almost remains the same (between 30% and 60%), requiring high level peri-operative care and prolonged hospital stay[8].

Fast-track surgery (or enhanced recovery after surgery) is an interdisciplinary, multimodal concept designed to accelerate postoperative recovery. The objectives of fast-track surgery are to reduce postoperative morbidity and reduce hospital stay time leading to an earlier return to normal life. The multimodal concept was first introduced in colonic surgery. Several studies have demonstrated the effectiveness of this programme in colonic resection[9 -17]. Most centres have implemented fast-track protocol in colorectal surgeries and these are now being extrapolated to other abdominal surgeries. Recently, fast-

track surgery has been proposed in pancreatic surgery with encouraging results, but such data are sparse[8, 18, 19]. There has been no previous attempt at implementing fast-track surgery in PD with pancreatico-gastrostomy as part of reconstruction. There has been hesitation in implementing fast-track programme after pancreatico-gastric anastomosis following PD, the reason being the fear of precipitating a leak.

Fast-track programme combines various techniques used in the care of patients undergoing elective surgery like epidural or regional anaesthesia, minimally invasive techniques, optimal pain control and aggressive postoperative rehabilitation, including early enteral/oral feeding and ambulation. Most of the randomised trials on fast track surgery did not demonstrate any significant difference in terms of quality of life, patient satisfaction, nutritional recovery or postoperative lean body mass deterioration[10]. However a safe early discharge from the hospital by itself is a favourable outcome. Recent published studies have confirmed no increase in morbidity and mortality by adhering to these principles. But there are very few such studies and further studies are warranted.

Randomised controlled trials have also indicated that there needs to be changes made in rehabilitation following upper gastrointestinal surgeries. These include selective or non-utilisation of nasogastric tube, avoidance or early removal of drains and early initiation of enteral feeding. The above three policies may greatly contribute to the reduction in morbidity or mortality by avoidance of many of the complications associated with their use. Some of these complications include sinusitis, esophagitis and aspiration pneumonitis associated with nasogastric tube use, ascending infections associated with drain tubes and avoidance of gut mucosal atrophy and bacterial translocation secondary to it by early initiation of enteral feeding. These measures obviously contribute to increased patient comfort and possibly to early recovery.

By reducing the common known stress responses in surgery, it might be possible to reduce complication rates and to achieve rapid recovery[8]. Comprehensive programmes have been developed with an aim to reduce post-operative hospital stay, through a coordinated effort of patient education, newer anesthetic and analgesic methods, pharmaceutical interventions, focused nursing, and mobilization actions[20]. Safety still remains the primary concern in implementing fast-

track protocol in major surgeries like pancreatic resections and the positive results need to be confirmed by randomised controlled trials.

There have been very few studies world over and probably ours is the pilot study from India, evaluating fast-track protocol in major pancreatic surgeries like PD. The implementation of fast track principles following PD may reduce stress response following the major surgery, thereby helping reduce complication rate and promote early recovery.

In this background it is valid to evaluate these fast track protocols after PD, in a high volume tertiary care centre like ours where about 60 pancreaticoduodenectomies are done each year with a mortality rate of < 1 %. Such a study as this would also help to provide more data about these post operative rehabilitation protocols in Indian population following major surgeries like pancreaticoduodenectomies and to assess if it reduces the financial burden on the health care system.

AIM OF THE STUDY

AIM OF THE STUDY

1. To evaluate the feasibility and safety of implementing fast track rehabilitation protocol following pancreaticoduodenectomy with pancreaticogastrostomy.
2. To evaluate whether fast track rehabilitation principles following pancreaticoduodenectomy is associated with faster recovery, reduced morbidity and reduced length of hospital stay.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

The surgical treatment of carcinoma head of pancreas and periampullary carcinomas had greatly evolved over the past 100 years. The first enbloc pancreaticoduodenectomy for an ampullary carcinoma was done by Codivilla, but this patient succumbed in the postoperative period[21]. In 1912, Walther Carl Eduard Kausch, a German surgeon, performed the first successful two-stage pancreaticoduodenectomy[22]. It was in 1935; Allen Oldfather Whipple presented three cases of a two-stage operation for the resection of carcinoma in the ampullary region. In the 1940s, he began performing a single-stage procedure, which involved reconstruction with an end-to-end choledochojejunostomy, an end-to-side pancreaticojejunostomy, and an end-to-side gastrojejunostomy[23]. The initially performed pancreaticoduodenectomies had poor outcomes and the mortality ranged close to 25%, even in the 1960s and 1970s. This led to the procedure being condemned by many surgeons. The mortality rate has dramatically reduced over the past two decades[24 – 26]. Currently most of the high volume centres report a mortality rate of < 4%[7, 24 – 26]. This has been attributed to technical advancements in surgery, improvements in surgical techniques, anaesthetic and peri-operative care. The long term

outcome after surgery for pancreatic malignancy has been dismal. The 5 year survival has been just about 25% even after achieving an R0 resection which falls to less than 10% if the resection margins are positive[26].

With the success of reducing mortality following PD to less than 5%, the focus now has shifted towards reducing morbidity following pancreatic resections. Even after all these years and the improvements in peri-operative care, the morbidity has not come down significantly and may reach about 50%[8]. The most prevalent complications following PD are delayed gastric emptying, pancreatic anastomotic leak leading to fistula, wound infection and post pancreatectomy haemorrhage.

Delayed Gastric Emptying:

DGE is the most common and distressing complication following PD with an incidence ranging between 19 – 57%[26 – 30]. This is one of the major factors contributing to increased length of hospital stay. The mechanism of DGE after PD is poorly understood with various hypothesis. The reasons are multifactorial; duodenal resection with a reduction in the length of the remaining duodenum, disruption of the vagal and sympathetic innervations to the antropyloric region and the decrease of plasma motilin after surgery have been implicated as the reasons for DGE[31 – 35]. Various definitions have been adopted in various studies, indicating the conundrum associated with defining DGE. The differences in the extent of resection, extent of lymphadenectomy and the method of reconstruction (gastrojejunostomy vs duodenojenunostomy or antecolic vs retrocolic gastrojejunostomy) have been suggested to have an impact on the occurrence of DGE. The difference in the type of surgical procedure between centres has been one of the major reasons contributing to the lack of a generally accepted definition of DGE in the past. The most common definition used in previous studies is the persistence of naso-gastric tube (NGT) ≥ POD 10 with additionally one of the following:

(a) emesis after NGT removal,

(b) use of prokinetics > POD 10,

(c) reinsertion of NGT,

(d) failure to progress with diet;

(2) NGT < POD 10 plus two of (a) to (d)[32].

Subsequently in 2007 the International Study Group of Pancreatic Surgery (ISGPS) introduced a revised definition for DGE with three grades[36] (Table. 1). The new definition and grading of DGE has become the standard definition and most of the centres have begun using it as a routine. The use of a uniform definition makes it possible to compare the results of different studies.

Table 1: ISGPS grading of DGE following pancreatic surgery.

DGE grade	NGT required	Unable to tolerate solid oral intake at:	Vomiting/gastric distension	Use of prokinetics
A	4 – 7 days or reinsertion after POD 3	POD 7	Yes/no	Yes/no
B	8 – 14 days or reinsertion after POD 7	POD 14	Yes	Yes
C	> 14 days or reinsertion after POD 14	POD 21	Yes	Yes

POD – Post operative day.

The various factors affecting the incidence of DGE after PD have been extensively analysed in various studies. DGE is seen after both classical PD and pylorus preserving PD (PPPD). There is controversy regarding which type of resection is associated with a reduced DGE. Some studies have found a higher incidence of DGE with pylorus preserving PD[1, 37 – 40] whereas others claim the contrary to be true[41 – 45]. Similarly, an antecolic gastrojejunal reconstruction after resection is said to be associated with a reduced DGE when compared to a retrocolic reconstruction[46, 47]. Post-operative complications are postulated to increase the incidence of DGE. Particularly, pancreatic fistula, peripancreatic collection or an intra-abdominal abscess can contribute to the patient developing DGE. Though DGE may not be life threatening by itself, it can cause discomfort, increase the duration of postoperative hospital stay, increase hospital costs, and decrease the quality of life postoperatively[36]. Fast-track surgery in pancreas is mainly aimed at reducing DGE and thereby duration of stay in the hospital and treatment cost.

The various components included in the definition of DGE are the following:

Naso-gastric tube (NGT): In some of the high volume centres, the NGT is removed as early as feasible (at 6 hours after surgery). There are reports when NGT is removed even when the patient is extubated. So the old definition of DGE: persistence of NGT > 10 days is considered outdated[36]. The ISGPS definition of DGE as need for NGT > 3 days seems appropriate as this would not miss out mild cases of DGE.

Oral intake: It is customary to start liquid diet at the earliest. In many of the centres, liquid diet is started on the first POD or the first day after removal of the NGT. Once patients are able to tolerate liquid diet, they are progressed on to semisolid diet and finally to solid diet. Patients are expected to tolerate solid diet by the 7^{th} POD. If they are not able to do so, it amounts to DGE.

Grade A DGE is the mildest form and does not require any marked change in the post-operative management. The patients recover without much problem apart from the delay in instituting oral liquid and solid diet. Patients with Grade B or C DGE require support in the form of prokinetic drugs and enteral or parenteral nutrition. Many centres add a feeding jejunostomy with PD, so that there is an access for easy enteral feeding if the patient develops DGE. Grade C DGE is usually associated with other complications like pancreatic fistula or intra-

abdominal collection or abscess. They may be associated with significant delay in discharge and there by delay in starting adjuvant therapy.

Panceatic fistula (PF):

The incidence of PF following PD is highly variable, ranging from as low as 2% to as high as 20% in the past[1, 7, 48, 49]. Pancreatic fistula is the second commonest complication following PD, next only to DGE. PF can contribute by increasing the incidence of DGE. Like DGE, PF also did not have a standard definition. The incidence of PF varied among centres, according to the definition used. There were four different definitions for PF in literature in the past (Table. 2).

Table 2: Different definitions of pancreatic fistula.

Four different definitions of pancreatic fistula according to literature
1. Output > 10 mL/d of amylase-rich fluid postoperative (postop) day 5 or for > 5 days.
2. Output > 10 mL/d of amylase-rich fluid after postop day 8 or for > 8 days.
3. Output between 25 mL/d and 100 mL/d of amylase-rich fluid after postop day 8 or for > 8 days.
4. Output > than 50 mL/d of amylase-rich fluid after postop day 11 or for > 11 days.

Synonymous terminologies commonly used to mean the same entity are pancreatic fistula, anastomotic leak, anastomotic failure and anastomotic insufficiency. After a list of different ways to define pancreatic fistula, a common acceptable definition of PF was needed to help compare results. Later in 2005, the International Study Group of Pancreatic fistula (ISGPF) introduced the new definition with 3 grades[50] (Table 3). This is the most common definition use today.

Table 3: ISGPS grading of PF following pancreatic surgery.

	Grade A	Grade B	Grade C
Clinical conditions	Well	Often well	Appearing ill
Specific treatment	No	Yes/no	Yes
US/CT (if obtained)	Negative	Negative/positive	Positive
Persistent drainage (after 3 weeks)	No	Usually yes	Yes
Re-operation	No	No	Yes
Death related to POPF	No	No	Possibly yes
Signs of infections	No	Yes	Yes
Sepsis	No	No	Yes
Readmission	No	Yes/no	Yes/no

POPF – Post operative pancreatic fistula

Pancreatic fistula can be generally defined as an abnormal communication between the pancreatic ductal epithelium and another epithelial surface containing pancreas derived, enzyme-rich fluid. Pancreatic fistula can result from a failure of healing of the pancreatic-enteric anastomosis or direct leak from a raw pancreatic surface. The amylase rich fluid can be seen draining from the drain tubes or from percutaneous drain tubes subsequently placed under image guidance. The fluid can be clear, milky water, dark brown or rarely greenish if it is close to a bilioenteric anastomosis. Radiological documentation is not required for making a diagnosis of PF.

Patients with grade A PF have no deviation from routine post-operative management. They make a normal recovery apart from a delay in the removal of drain tubes. Grade B PF requires changes in the post-operative management in the form of keeping the patient nothing by mouth, enteral nutrition usually through feeding jejunostomy tubes, partial or total parenteral nutrition, repositioning of drain tubes under image guidance or somatostain analogues. Patients with Grade C PF require major changes in the post-operative care. In addition to those measures as in grade B pancreatic fistula, patients usually need

management and monitoring in an intensive care unit with extended hospital stay and a significant delay in discharge.

In an attempt to reduce the morbidity and the prolonged hospital stay associated with pancreatic fistulas, various modifications of pancreatic anasotomosis have been attempted. Technical modifications such as pancreatic duct occlusion, reinforcement of anastomosis with fibrin glue, placement of internal stent, and pancreaticogastrostomy as opposed to pancreaticojejunostomy have been tried, but with no significant improvement in the rate of PF[51 – 55]. The somatostatin analogue, octreotide has been used in an effort to reduce the incidence of PF. But a meta-analysis did not find any benefit of using octreotide in reducing PF following PD[51]. Later external drainage of the pancreatic duct using an intra-ductal stent across the anastomosis in a duct to mucosa pancreaticojejunostomy (PJ) was tried. It was postulated that by diverting the pancreatic juice away from the anastomosis, it would reduce the incidence of anastomotic leakage from PJ. There are prospective non-randomised as well as randomised studies showing that such external drainage of the pancreatic duct decreased the rate of pancreatic fistula[56, 57].

Post Pancreatectomy Haemorrhage (PPH):

Post pancreatectomy haemorrhage is a less common complication following PD, but could be significant and fatal at times. Gastrointestinal or intra-abdominal haemorrhage occurs in about 1 – 8% of pancreatic resections and account for about 11% to 38% of overall mortalities following surgery[58 – 60]. The bleed can be intraluminal or extraluminal. PPH can be classified on the basis of 3 criteria: (I) time of onset, (II) location and cause, and (III) severity.

Based on the time of onset, PPH can be differentiated into early and late. Previous studies have used 5 or 7 days as the cutoff to define early and late PPH. According to the recent ISGPS criteria, early PPH is defined as that occurring in the first 24 hours postoperatively, i.e. 24 hours after the end of the index operation, and late PPH occurring more than 24 hours postoperatively[61]. Early PPH is usually due to technical failure, lack of appropriate hemostasis during surgery or an underlying uncorrected perioperative coagulopathy. Late PPH commonly occur days or weeks after the surgery[4, 58, 62]. Late PPH may occur due to complications of the surgery like intraabdominal abscesses, erosion of a peripancreatic vessel secondary to pancreatic fistula or by an intra-abdominal drain, ulceration at the site of an anastomosis, or from an

arterial pseudoaneurysm that has developed following surgery (the commonest site being the gastroduodenal artery).

PPH may originate from one of the following sites[30, 58, 63 – 66]:

(a) arterial or venous vessels in the peripancreatic region.

(b) suture lines of the anastomoses involved in reconstruction (gastroenteric, duodenoenteric, jejunojejunal or pancreaticoenteric).

(c) raw areas following resection (eg, pancreas stump, retroperitoneum).

(d) gastric/duodenal ulcer or diffuse gastritis which has developed in the post-operative period.

(e) eroded and ruptured pseudoaneurysms.

(f) hemobilia from previously placed endobiliary stents.

Possible pathophysiologic explanations for late PPH include enzymatic digestion of the blood vessel wall by trypsin, elastase, and other pancreatic exocrine enzymes secondary to a pancreatic leak. Other reasons could be intra-abdominal infection and collection with involvement of peripancreatic vessels or vascular injury during

resection that leads to a pseudoaneurysm[60, 67]. Vascular structures close to the pancreas like the stump of the gastroduodenal artery, splenic artery, branches of the superior mesenteric artery (eg, inferior pancreaticoduodenal artery), the splenic vein stump or rarely, an intrapancreatic artery can be the source of bleed.

There are many classifications of PPH based on the severity. Earlier studies classified it as mild or severe. PPH can be termed mild, when there is no clinical impairment or requirement for blood transfusion. It falls in the severe category when more than 4 or 6 units of packed cells are transfused within 24 hours or there is a decrease in hemoglobin of more than 4 g/dl[68, 69]. The ISGPS definition categorise PPH as mild and severe types (Table. 4, 5). The categorization of PPH into mild or severe type mainly depends mainly on clinical and biochemical parameters, and the requirement of blood transfusion. At times the difference can be subtle. A patient who is considered to have mild PPH may develop a rebleed and shift to the severe category.

Table 4: Definition of severity of PPH.

Mild	- Small or medium volume blood loss (from drains, nasogastric tube, or on ultrasonography, decrease in hemoglobin concentration < 3 g/dl). - Mild clinical impairment of the patient, no therapeutic consequence, or at most the need for noninvasive treatment with volume resuscitation or blood transfusions (2-3 units packed cells within 24 h of end of operation or 1-3 units if later than 24 h after operation). - No need for reoperation or interventional angiographic embolization; endoscopic treatment of anastomotic bleeding may occur provided the other conditions apply.
Severe	- Large volume blood loss (drop of hemoglobin level by ≥ 3 g/dl). - Clinically significant impairment (eg, tachycardia, hypotension, oliguria, hypovolemic shock), need for blood transfusion (> 3 units packed cells). - Need for invasive treatment (interventional angiographic embolization, or relaparotomy).

The differentiation is mainly for the sake of characterization and documentation. Even a mild PPH warrants the same vigilant monitoring of the patient as required in severe PPH. However, the outcomes are likely to be different.

Table 5: ISGPS grading of PPH following pancreatic surgery.

Grade	Time of onset, location, severity and clinical impact of bleeding		Clinical condition	Diagnostic consequence	Therapeutic consequence
A	Early, intra- or extra luminal, mild		Well	Observation, blood count, US and, if necessary, CT	No
B	Early, intra- or extra luminal, severe	Later, intra- or extra luminal, mild	Often well/intermediate, very rarely life-threatening	Observation, blood count, US, CT, angiography, endoscopy	Transfusion of fluid-blood, intermediate care unit (or ICU), therapeutic endoscopy, embolization, relaparotomy for early PPH
C		Late, intra- or extraluminal, severe	Severely impaired, life-threatening	Angiography, CT, endoscopy	Localization of bleeding, angiography and embolization, (endoscopy) or relaparotomy, ICU

In grade A PPH, there is only a marginal deviation from the routine post-operative course of the patient. It does not have a major clinical impact or cause a significant delay in the patient's discharge. Grade B PPH requires deviation from routine in the form of diagnostic investigations and therapeutic interventions. Patients may require blood transfusions, admission to an intermediate or intensive care unit. These patients frequently mandate potential invasive therapeutic interventions such as relaparotomy or angioembolization. As a consequence patients with grade B PPH usually have a prolonged hospital stay. Grade C PPH causes severe impairment of the patient and is potentially life threatening. Immediate diagnostic and therapeutic interventions are required. Patients may not be stable enough for angioembolisation and emergency re-exploration may be required. Patients frequently require prolonged stay in the intensive care unit. The mortality rate associated with grade C PPH is significantly high. There is usually a sentinel bleed which preceeds the bout of massive haemorrhage. It is recommended that when a sentinel bleed is seen, immediate angiography should be considered as an option for definite treatment or to bridge time to stabilize and prepare the patient for a relaparotomy[70].

Drain tubes:

Prophylactic intra-abdominal drain tubes are usually placed after PD to help monitor and facilitate early identification of pancreatic fistula and PPH[67, 71]. So prophylactic drain tubes are placed following PD even in high volume centres and are usually removed around the 7th post operative day[7, 43, 72]. But placement of intra-abdominal drains is associated with increased rates of intra-abdominal and wound infection, increased abdominal pain, decreased pulmonary function, and prolonged hospital stay[49]. A randomised control trial has shown that drain tubes are not mandatory and can be omitted with no increase in morbidity[49]. Early removal of drains was associated with a significantly decreased rate of pancreatic fistula, abdominal and pulmonary complications. These patients also had shorter median in-hospital stay and reduced hospital costs[73]. Patients with drain fluid amylase value ≤ 5000 U/L on the 1st post operative day are less likely to develop a pancreatic fistula and a delayed removal of drain tubes in these patients might increase the above mentioned complications[74]. Further randomised trials are warranted to evaluate andclarify whether drains help in reducing complications following PD. According to a recent

meta-analysis, even when drain tubes are placed, early removal of drains was found to be superior when compared to late removal[75].

Prophylactic Somatostatin analogues:

As somatostatin analogues reduce the endocrine and exocrine pancreatic secretions, they have been used prophylactically in an attempt to reduce pancreatic fistulas. The practice has been controversial with some studies supporting the use of somatostatin analogues while others contradict. The incidence of pancreatic fistula was less in the group of patients who received somatostatin. But there was no difference in the rates of clinically significant pancreatic fistula in these patients. Based on these evidence prophylactic somatostatins analogues were recommended routinely after pancreatic resections[76]. There are many centres which routinely use somatostatin analogues in the dose of 100 μgms thrice daily given subcutaneously. A higher dose has been practiced for high risk categories like a soft pancreatic parenchyma and a small pancreatic duct. Though somatostatin analogues have been routinely used in many centres, their efficacy in reducing pancreatic fistula needs further evaluation and evidence to recommend it.

Restricted peri-operative fluid infusion:

Restriction of peri-operative fluid infusion has been an integral part of fast-track protocol in colo-rectal surgery. Excessive fluid infusion is believed to promote submucosal intestinal oedema, reduce mesenteric blood flow, reduce tissue oxygenation, and cause intramural acidosis predisposing to anastomotic breakdown[77]. It is also said to contribute to post-operative ileus. On the contrary, excessive fluid restriction can cause hypovolemia and hypoperfusion leading to organ dysfunction. Therefore a balance needs to be struck between these two situations. The effect of restricting peri-operative fluid infusion is still not clear and is presently at the discretion of the anaesthesiologists. The rates of fluid infusion are usually adjusted according to the haemodynamic status of the patient and the urine output. Further studies are required to make a definite recommendation.

Epidural analgesia:

Thoracic epidural analgesia is also a basic requisite of the fast-track protocol. The advantages of epidural analgesia are the reduced requirement of anesthetics, improved pain control, reduced incidence of cardiac and pulmonary complications, reduced surgical stress response and early bowel recovery[78]. But epidural analgesia is not without problems. About one third of epidural infusions need to be stopped because of haemodynamic instability. A significant proportion of patients require analgesic supplementations because of inadequate analgesia[78]. In one study the use of epidural analgesia did not alter the bowel function, lengths of stay, morbidities, or mortality[79]. But most centres routinely use epidural analgesia as it offers better pain relief, allows the patient to ambulate earlier and enables the patient a better respiratory function in the post-operative period. Indirectly these benefits may translate into early recovery of the bowel function and a shorter hospital stay, though these entities have not been proven. Further randomised controlled studies to evaluate the effect of epidural analgesia in major procedures like pancreaticoduodenectomy are unlikely, as it has become an integral part of the peri-operative management.

Naso-gastric tube (NGT) decompression:

Naso-gastric tubes are routinely introduced after all major abdominal surgeries including pancreaticoduodenectomy as it has been thought to decrease postoperative ileus, respiratory complications, and the incidence of anastomotic leaks[80]. But these effects have not been proven and the benefits of a routine NGT have recently been questioned. The high incidence of DGE following PD has discouraged surgeons from eliminating the routine use of naso-gastric tube. Two case-control studies have shown that avoiding the routine use of nasogastric suction resulted in no increase in morbidity or mortality[81, 82]. There was no difference in the rate of delayed gastric emptying, anastomotic leak, wound infection, wound dehiscence, and pneumonia. The routine use of naso-gastric tube also increased patient's discomfort following surgery. The use of naso-gastric tube as a routine following PD needs to be reconsidered, despite the apprehension associated with avoiding it. Even when used, it seems ideal to remove them earlier. There are a few centres which remove the NGT in the operating room on recovery. Majority of patients do not require NGT after the first or the second post-operative day. Early removal of NGT seems to be

beneficial and must be the routine unless there are specific indications to retain them.

Early Ambulation:

Early ambulation is believed to have an effect on the post-operative functional recovery. The benefits of early ambulation include a reduced risk of deep vein thrombosis of the lower extremities, early recovery from post-operative ileus, reduced pulmonary complications and the possibility of an early removal of bladder catheter thereby reducing the risk of urinary infection[83]. However there are no studies to evaluate and prove these benefits following pancreatic surgery. Most of these effects have been extrapolated from colo-rectal surgeries. Fast-track programmes have aimed at ambulating patients early in the post-operative period to achieve these benefits. Early ambulation by itself might give the patient a sense of well being and prepares the patient psychologically for an early discharge.

Early oral feeds:

Post-operative oral intake is thought to be associated with increased vomiting, higher post-operative ileus and the possibility of anastomotic leak. So, oral feeds are usually introduced after the patient regains bowel function (appearance of bowel sounds). But there is no evidence to support this practice and early post-operative oral intake on the contrary, is suggested to be beneficial[84]. According to a meta-analysis, early enteral nutrition following pancreatic surgery was associated with a lower incidence of post-operative complications[85]. Now, most of the high volume centres begin to feed patients who have undergone PD on the 2nd post-operative day. There are centres that start oral liquids as early as 6 hours after surgery. Some studies have shown that starting early enteral feeds reduces DGE and PPH[86]. Enteral feeds also have the benefit of maintaining the intestinal mucosal integrity thereby reducing bacterial translocation across the bowel, which is considered an important source of sepsis.

Enhanced recovery (fast-track) concept:

Post-operative hospital stay after PD depends mainly on complications including pancreatic fistula, post-pancreatectomy hemorrhage, delayed gastric emptying, and general medical complications involving the cardiopulmonary systems. After the mortality rates after PD have fallen there has been an increased emphasis on achieving an uneventful post-operative period and reducing the length of hospital stay. Achieving this would amount to early discharge of the patient and return to a familiar environment earlier with a reduction in the treatment cost[87]. "Enhanced recovery" or "fast-track" concepts have been introduced with an aim to facilitate early recovery after surgery and restore the functional capacity of the patients to the normal pre-operative state earlier. Most of the reports on fast-track programmes have shown reduction in the hospital stay and the treatment cost involved. This was not associated with proportionate decrease in the incidence of complications or mortality. It is questionable, whether the noted benefits resulted from improvements in physiological factors related to patient recovery or potentially from a more efficient discharge policy[88]. In addition to these factors, economic, social and logistic factors influence the length of hospital stay. Post-

operative hospital stay is longer in the eastern world than in the United States or Europe. In the east, patients are discharged only when they feel confident and comfortable. Of late the importance of early recovery and discharge has been realized world over. The only factor which needs to be considered while introducing fast-track programmes is patient safety. Such programmes need to be promoted, but not at the expense of increased morbidity or complications. When considering major procedures like PD, these programmes have been used with hesitancy. Very few studies have endorsed the efficacy and safety of fast-track protocol following pancreaticoduodenectomy. Further studies are warranted to prove the safety of these programmes following PD.

MATERIALS & METHODS

MATERIALS AND METHODS

Study Design:

Prospective analysis and comparison with historical control

Study Period:

April 2012 to December 2012

Study Setting:

Institute of Surgical Gastroenterology and Liver Transplantation, Government Stanley Medical College and Hospital, Chennai.

Inclusion Criteria:

All patients undergoing pancreaticoduodenectomy for either one of the following diagnoses in the study period were included in the study.

Carcinoma head of pancreas

Periampullary carcinoma

Distal common bile duct (CBD) growth

Duodenal growth

Chronic calcific pancreatitis with pancreatic head mass

Any tumour / suspicious lesion in the head of pancreas requiring resection

Exclusion Criteria:

1. Denial of consent by the patient.
2. Preoperative organ system failure.
3. ASA – IV/V.
4. Contraindication of one or more fast track strategies.

Methodology:

Fast-track rehabilitation protocol following PD was introduced in the Department of Surgical Gastroenterology and Liver Transplantation, Stanley Medical College, Chennai, in April 2012. Twenty one patients underwent PD between April 2012 and December 2012, out of which 20 patients who met the inclusion criteria were included in the study. One patient was excluded because patient had coagulopathy which prevented epidural analgesia. The patient also required prolonged post-operative ventilator support. These patients were compared with previous consecutive similar number of patients who underwent PD and were managed according to the traditional pathway.

Pre-operative parameters – detailed demographic profile, clinical symptoms with duration, clinical findings, blood investigation reports (complete blood counts, renal function test with electrolytes, blood sugar, liver function test), viral marker status (HBsAg and Anti-HCV), upper gastrointestinal endoscopy, findings of radiological imaging (X-ray of the chest, ultrasonogram [USG] of the abdomen with doppler, contrast enhanced computed tomogram [CECT] or magnetic resonance

imaging [MRI]) and CA 19-9 values (in requiring patients) were recorded.

After assessing for operability, all patients underwent classical pancreatico-duodenectomy involving resection of the head and uncinate process of pancreas along with the pylorus of stomach, distal portion of CBD upto the level of cystic duct insertion with the common hepatic duct, whole of duodenum and the proximal portion (about 20 cms) of jejunum. Reconstruction included anastomosis in the form of end to side pancreatico gastrostomy to the posterior wall of stomach by dunking method in a single layer, end to side hepatico jejunostomy in single layer, end to side gastrojejunostomy 30 cms distal to the hepaticojejunostomy in two layers and a feeding jejunostomy 30 cms distal to gastrojejunostomy by modified Witzel's technique using a 10 French infant feeding tube. One or more intra-abdominal drain tubes were placed during surgery. A naso-gastric tube was left in situ. The operations were performed by team of 5 surgeons.

Intra-operative parameters including duration of surgery, intra-operative blood loss, amount of fluids infused intra-operatively, number of units of blood transfused and any intra-operative events will be recorded.

All patients received the same post operative care and rehabilitation according to a newly adapted “fast-track rehabilitation protocol” (fast track group). Patients were extubated in the operating room or in the post-operative ward, on the day of surgery. Epidural analgesia as infusion was provided in all the patients. NSAIDs or opioids were given if epidural analgesia was ineffective or as rescue analgesia. Prophylactic antibiotics were given in all the patients. Prophylactic pancreatic secretion inhibition with octreotide was not used in any of the patients. All patients received metoclopramide (30 – 60 mg) on the 1st post operative day (POD) to reduce nausea and vomiting.

The naso-gastric tube was removed on the 1st POD if the volume draining was less than 300 ml. Trickle feeds of about 20 – 30 ml / hour, through the feeding jejunostomy was started on the first POD. Patients were mobilized out of bed for a minimum of one hour on the first POD. The mobilization was gradually increased each day till the patient was out of bed for more than 4 hours on the 3rd POD. The drain tube amylase levels were checked on the 3rd POD, 7th POD and subsequently each week if the drain tube was retained. The intra-abdominal drain tubes were removed on the 3rd POD if there was no pancreatic or biliary

fistula and the volume was less than 200 ml. Oral diet was increased from liquid diet to semisolid diet and finally to solid diet. It was attempted to start the patient on solid diet on the 4th POD.

All patients were initially nursed in a post operative high dependency unit and later shifted to the routine ward when fit and appropriate; when patients were free of nausea or vomiting, reasonably pain free, able to sit comfortably, adequately ambulant and able to walk to the toilets. All post-operative events (time to remove nasogastric tube, time to tolerate oral liquids and solids, time to pass stools, time to remove drain tubes, length of hospital stay and readmission rate) complications (delayed gastric emptying, pancreatic fistula, post operative haemorrhage, biliary leak, bilioma & fistula, abdominal collection or abscess, peritonitis, wound complications, pulmonary, cardiac and renal complications) and mortality were recorded.

The demographic profile, pre-operative parameters, intra-operative parameters, post-operative recovery, complications, morbidity and mortality of the patients in the fast-track group were compared with those of the patients treated by the conventional pathway (conventional group). The conventional pathway included nasogastric decompression until post operative day 5, oral liquids from day 6 and soft solid diet

from day 7; no specific action on mobilisation was defined. Apart from the specific changes mentioned, the other post-operative management was not different between the two groups.

All data were collected prospectively and analysed retrospectively in the fast-track group, where as some data like the incidence of nausea, vomiting and the first instance of passing flatus in the conventional group were retrospectively collected. Because of the inaccuracies of the retrospectively collected data, these factors were not considered for analysis. Postoperative complications were defined as those occurring while the patient was in-hospital and within 30 days of discharge. Mortality was defined as in-hospital death, irrespective of duration of stay, or death occurring within 30 days of discharge. Delayed gastric emptying (DGE), pancreatic fistula (PF) and post pancreatectomy haemorrhage (PPH) were defined according the definitions of the International Study Group for Pancreatic Surgery (ISGPS) [21, 22, 50]. Details of readmission were collected from the follow up data.

Statistical analysis:

All patients operated after introduction of the protocol for fast-track rehabilitation following PD were considered to belong to the fast-track group even if they did not accomplish the protocol (intent-to-treat analysis). An equal number of patients treated by the conventional protocol, before the fast-track programme was introduced were included in the control (Conventional) group. Categorical variables were compared with the Fischer's exact test, quantitative variables with Student's t test and nonparametric continuous variables with Mann–Whitney U test. A p value of < 0.05 was considered significant. Data analysis was performed with SPSS version 13.0 (SPSS, Chicago, Illinois, USA). All values are presented as mean with standard deviation (SD), median with range or percentages.

Protocol for fast-track programme after pancreatico duodenectomy

Preoperative:

Preoperatively patients were informed about the fast-track programme, including daily milestones.

Intraoperative:

Thoracic epidural was inserted for post-operative analgesia.

Postoperative:

Day 0: Epidural analgesia ± Opioids / NSAIDs

Day 1: Removal of Nasogastric tube if < 300 ml

Mobilisation out of bed for > 1 hour

Trickle feeding through feeding jejunostomy

Day 2: Enhanced mobilization for > 2 hours

Urinary catheters removed

Day 3: Clear oral liquids

Removal of drainage tubes if no pancreatic or biliary fistula and volume less than 200 ml

Mobilisation for > 4 hours

Day 4: Soft solid diet

Day 5: Dietary increase on daily basis

Epidural catheter removal

Pharmacological support:

Metacloperamide up to 60 mg/day iv – used to prevent nausea and vomiting

Discharge criteria:

Patients were considered fit to be discharged if they satisfied the following criteria.

Absence of fever for > 48 hours

Adequate pain control with oral analgesics

Able to take solid food

Passage of normal stools

Adequate mobilization

Acceptance of discharge by the patient

RESULTS

RESULTS

Demographic and intra-operative variables:

The two groups were similar in regards to demographic profile, clinical factors, pre-operative serum bilirubin and albumin levels (Table. 6). The mean (± standard deviation) age of patients was 44.2 ± 15.9 in the fast-track group and 47.6 ± 12.0 in the conventional group ($p = 0.45$). The male : female ratio was also similar between the two groups; 9:11 in the fast-track group and 10:10 in the conventional group. There was a higher incidence of co-morbidities (7 vs 2; $p = 0.12$) in the conventional group, but it was not statistically significant. The indication for PD was also comparable between the two groups; periampullary carcinoma being the most common indication, accounting for about 50% of the cases in both the groups. The other frequent indications were carcinoma head of the pancreas, distal CBD growth or duodenal carcinoma (Table. 7). There was one patient with a neuroendocrine tumour and one patient with metastasis from a previously operated renal cell carcinoma of the kidney. Benign indications were solid pseudo papillary neoplasm in the head of pancreas in three patients, a serous cystadenoma and a duodenal polyp with intussusception.

The duration of surgery was slightly longer in the conventional group, but was not significant (mean ± standard deviation 386 ± 73.51 vs 422.25 ± 58.99 ml; p = 0.09). The blood loss during surgery and the number of units of blood transfused were also similar in the two groups. The volume of intra-operative fluids used was significantly less in the fast-track group (mean ± standard deviation 2852.5 ± 788.14 vs 3600 ± 596.48; p = 0.001). Vascular resections were not required in any of our patients.

Table 6: Demographic and perioperative parameters in patients treated according to fast track and conventional pathway.

	Fast track (n = 20)*	Conventional (n = 20)*	P
Age	44.2 ± 15.9	47.6 ± 12.0	0.45
Sex (M:F)	9:11	10:10	1
Co-morbidities	2	7	0.12
Preoperative bilirubin	8.02 ± 8.09	5.98 ± 6.30	0.37
Preoperative albumin	3.81 ± 0.41	3.57 ± 0.42	0.07
Duration of surgery (min)	386 ± 73.51	422.25 ± 58.99	0.09
Blood loss (ml)	357.5 ± 160.4	403.25 ± 159.77	0.37
No. of patients transfused	6	8	0.74
Intraoperative fluids (ml)	2852.5 ± 788.14	3600 ± 596.48	0.001

* Values are mean with standard deviation.

Table 7: Indications for surgery.

Diagnosis	Fast track	Conventional
Periampullary carcinoma	9	11
Carcinoma head of pancreas	3	1
Distal CBD growth	2	3
Duodenal carcinoma	1	3
Solid pseudopapillary neoplasm	3	-
Neuroendocrine tumour	1	-
Metastasis from RCC kidney	1	-
Serous cystadenoma	-	1
Duodenal polyp	-	1

Post-operative course:

The naso-gastric tube inserted during surgery, was removed on a median of 4 days (range, 1 – 11) in the fast-track group and on a median of 7 days (range, 4 – 13) in the conventional group (Table. 8). This was statistically significant with a p value of 0.008. Patients were started on oral liquids as soon as the naso-gastric tube was removed. Oral diet was increased in a step-like fashion from liquid diet, through semi-solid diet to solid diet. Patients usually tolerated solid diet within two days of starting liquid diet, if there were no complications. The naso-gastric tube was reinserted in 3 patients in the fast-track group (days 9, 11 and 12) and in one patient in the conventional group. In the fast-track group, it was because 3 patients were taken up for re-laparotomy. The one patient in the conventional group developed abdominal distention and bilious vomiting, requiring reinsertion of the naso-gastric tube on post-operative day 7. Patients were able to tolerate liquid and solid diet significantly earlier in the fast-track group when compared to the conventional group; p values were 0.0005 and 0.0001 respectively. Patients also passed stools earlier in the fast-track group (p = 0.02).

Most of the patients had two closed drain tubes placed in either flanks. Both the right and the left side drain tubes were removed earlier in the fast-track group (right drain tube: median 5 vs 8 days; $p = 0.04$ and left drain tube: median 7.5 vs 9 days; $p = 0.004$). Patients were shifted from the post-operative high dependency ward to the routine ward when they were free of vomiting, reasonably pain free, able to sit comfortably, adequately ambulant and able to walk to the toilets. The number of days the patients stayed in the post-operative high dependency ward was less in the fast-track group, but it was not statistically significant (median 6 vs 7 days; $p = 0.1$). The post-operative hospital stay was significantly shorter in the fast-track group (median 14 vs 18.5 days, $p = 0.007$). None of the patients were readmitted within a period of 30 days.

Table 8: Postoperative course in patients treated according to fast track and conventional pathway.

	Fast track (n = 20)*	Conventional (n = 20)*	P
Naso-gastric tube removed (days)	4 (1 – 11)	7 (4 – 13)	0.008
Oral liquid diet (days)	4 (2 – 19)	8.5 (4 – 22)	0.0005
Oral solid diet (days)	7 (3 – 23)	10.5 (7 – 25)	0.0001
Right drain tube removed (days)	5 (3 – 20)	8 (4 – 22)	0.04
Left drain tube removed (days)	7.5 (4 – 20)	9 (6 – 21)	0.004
Passed stools on (days)	4 (3 – 6)	5 (3 – 9)	0.02
Stay in high dependency ward (days)	6 (3 – 11)	7 (5 – 22)	0.1
Postoperative hospital stay (days)	14 (9 – 26)	18.5 (13 – 38)	0.007

* Values are median with range.

Post-operative complications:

Complications like intra-abdominal collection, atelectasis of the lung, urinary tract infection and wound infection were similar in the two groups. Delayed gastric emptying (DGE) was significantly lesser in the fast track group ($p = 0.02$). Seven (35%) patients in the fast-track group and 15 (75%) in the conventional group developed DGE (Table. 9). But most of the patients had grade A DGE; 57 % (4 out of 7) in the fast-track group and 66 % (10 out of 15) in the conventional group. The incidence of pancreatic fistula (PF) was similar in the two groups ($p = 1$). There were 11 and 10 patients with PF in the fast-track and the conventional groups respectively. But clinically significant PF (grades B and C) accounted for only 3 (15 %) patients in the fast-track group and one (5%) patient in the conventional group.

The incidence of post pancreatectomy haemorrhage (PPH) was also similar in the two groups. There were 4 patients with PPH in the fast-track group and 2 such patients in the conventional group. Out of these patients, 3 in the fast-track and one in the conventional group required re-laparotomy. In two patients the bleed was from the pancreas stump. The pancreas stump was reached through an anterior gastrostomy and the bleed was controlled by suture ligation. In one

patient the bleed was from a spurting vessel near the inferior aspect of the pancreas stump and in the last it was from a dilated vessel in the mucosal aspect of the body of the stomach. Both the patients required an anterior gastrotomy and suture ligation of the site of bleed.

There were 2 mortalities in the fast-track group and one in the conventional group. Both the mortalities in the fast-track group were related to PPH for which the patients were taken for re-laparomy. Post operatively both the patients developed pancreatic fistula leading on to sepsis and multi organ failure. The single mortality in the conventional group was due to a sudden massive pulmonary embolism. The patient had made a good recovery, but had wound infection for which secondary suturing was done. Patient succumbed to the massive pulmonary embolism.

Table 9: Morbidity and mortality in patients treated according to fast track and conventional pathway.

	Fast track (n = 20)	Conventional (n = 20)	P
Surgical complications	5	9	0.32
Re-laparotomy	3	1	0.6
Delayed gastric emptying			0.02
Grade A	4	10	0.03
Grade B	1	4	0.05
Grade C	2	1	1
Pancreatic fistula			1
Grade A	8	9	1
Grade B	1	1	1
Grade C	2	0	0.47
Post pancreatectomy haemorrhage			0.66
Grade A	1	1	1
Grade B	0	0	-
Grade C	3	1	0.6
Mortality	2	1	1

DISCUSSION

DISCUSSION

Advancement in the surgical techniques, better equipments and technology and better anaesthetic and peri-operative care have contributed significantly in reducing the mortality rates following pancreaticoduodenectomy to less than 5% in most of the high volume centres[1 – 7]. But they have not helped greatly reduce the morbidity rate and it still ranges between 30 and 60%[8]. Having brought about a reduction in the mortality, the focus now is towards enhancing recovery, reducing morbidity and shortening hospital stay. The high morbidity is associated with a higher physiological and psychological stress. In the last decade, a comprehensive multimodal peri-operative care programme, "fast-track programme", has been introduced. The aim of such a programme is to bring about a reduction in morbidity, a faster post-operative recovery and a shorter hospital stay. Following the success of the fast-track programme in colorectal surgery, it has been attempted in other gastrointestinal surgeries[9 – 17]. Recently, fast-track surgery has also been attempted with success in pancreatic surgery[8, 18, 19]. But there are very few studies and all previous studies are from centres which perform pancreaticojejunostomy following PD. This study has attempted to study the impact of fast-track protocol following

PD with pancreatico-gastrostomy. Though there is the possibility of a bias associated with using historical controls, the two groups were similar in demographic and peri-operative factors. The only difference was the increased volume of intravenous fluid infused intra-operatively, in the conventional group (mean ± SD 3600 ± 596.48 vs 2852.5 ± 788.14 ml; p = 0.001). This was partly due to the anaesthetic protocol of restricting fluid infusion to the required minimum, to prevent fluid overload intra-operatively and partly to the slightly increased operative duration in the conventional group. Apart from the changes listed in the protocol, patients in both the group were managed similarly. The patients in both the group were operated by the same team of surgeons, as it involved a short duration. This also avoided a change in the learning curve.

Most patients undergoing PD has significant nausea and vomiting, which prevented early enteral feeds. Contrary to earlier belief, nausea and vomiting was not precipitated by the early removal of naso-gastric tube. Retaining the naso-gastric tube for a longer duration only postponed the occurrence of nausea or vomiting and did not prevent it[18]. It also prolonged the discomfort of the patient[18]. There are recent data to suggest that routine naso-gastric tube is unnecessary

in elective abdominal surgery and can lead to increased incidence of pulmonary complications[89]. When pancreaticogastrostomy (PG) is done, there is a tendency to retain the naso-gastric for a longer duration in an attempt to decompress the stomach and reduce the risk of an anastomotic leak. But, it was possible to remove the naso-gastric tube in a median (range) of 4 (1 – 11) days with no increase in incidence of pancreatic fistula.

Patients were able to tolerate oral liquid and solid diet earlier in the fast-track group. This amounted to a significantly less DGE in the fast-track group when compared to the conventional group. It is also postulated that early post-operative feeding might improve gastric emptying and peristalsis in the intestine[90], thereby reducing DGE. DGE is one of the most common and distressing complications of PD, with reported rates of 20 – 30%[91]. Early ambulation is said to reduce post-operative ileus, but the issue is controversial[92]. The higher incidence of DGE in the present study (35% in the fast-track group and 75% in the conventional group) is due to the use of the International Study Group of Pancreatic Surgery (ISGPS) definition of DGE[93]. The earlier studies have used the previous commonly used definition: the need for a naso-gastric tube or emesis after day 10[4, 43, 93, 94]. Despite the increased

incidence of DGE, it was worthwhile to note that majority of the DGE belonged to grade A; 57% (4 out of 7) in the fast-track group and 66% (10 out of 15) in the conventional group.

Another significant finding was that starting the patient earlier on oral diet did not increase the incidence of pancreatic fistula. The higher incidence of PF in this study per se, is the consequence of applying the ISGPF definition for PF[50]. But similar to DGE, most of the PF belonged to grade A (8 out of 11 in the fast-track group and 9 out of 10 in the conventional group). These patients did not have a change in the course of post-operative recovery nor did they require any specific intervention. The incidence of clinically significant PF (grade B or C) was only 3 in the fast-track group and one in the conventional group. There was no difference in the rates of post pancreatectomy haemorrhage and other non-specific complications between the two groups. The mortality rate was similar and there was also no difference in the 30 day readmission rate.

Contrary to expectations, the length of stay in the post-operative high dependency ward was not different between the two groups. This was probably due to hesitancy in shifting patients to the general ward earlier, as these were the first set of patients treated by fast-track

surgery. Further experience might add confidence and help reduce the stay in the high dependency ward.

The most important difference was the decrease in post-operative hospital stay in the fast-track group. The reduced hospital stay was attributed mainly to the decrease in DGE, with patients tolerating oral diet earlier. Early ambulation with no increase in morbidity or complications added to the sense of well being and the patient's acceptance to return home. Length of hospital stay is an indirect indicator of the hospital cost involved. So, a shorter hospital stay amounts to a decrease in overall cost involved, as the implementation of fast-track programme did not involve any specific costly intervention.

CONCLUSION

CONCLUSION

Implementation of fast-track programme is associated with early recovery, early feeding, early passage of stools, early removal of drains and early discharge. Despite earlier concerns with fast-track surgery, it did not increase the complication rate, morbidity and mortality. Fast-track programme appears to be feasible and safe after pancreaticoduodenectomy, even with pancreatico-gastric anastomosis. This protocol is practical and can be easily introduced with no increase in cost. The reduced incidence of DGE might contribute to shorter hospital stay and eventually to a reduced treatment cost. Further studies are needed to evaluate the impact of fast-track approach and optimize the protocol. Experience in implementing the protocol might contribute to further enhancing recovery and reducing hospital stay, in high volume centres.

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APPENDIX

Impact of fast track rehabilitation protocol following pancreaticoduodenectomy

Patient's Details Proforma

Demographic profile:

Name: Age: Sex: M / F I.P. No:

Occupation: Income:

Address:

Date of Admission: Date of Surgery: Date of Discharge:

Length of hospital stay: Total: Days Post Op: Days

Clinical details:

Symptoms: Rt hypochondrial pain / Jaundice / Fever / Pruritus / Vomiting / Haematemesis / Melena / Anorexia / loss of weight/ Others –

Duration of Symptoms:

Treatment history: ERCP & Stenting / PTBD / Others –

Previous surgeries:

Family History: Alcoholic / Smoker

Co-morbidities: DM / HT / TB / BA / IHD / Hypothyroidism / Others

Details:

Clinical Examination: Hepatomegaly / Distended GB / Lymphadenopathy / Ascites / Distant Metastases

Others:

Investigations:

Hb:		PCV:		TC:		DC:	P % L % E % M				
ESR:		Platelets:		PT/INR:		Bl.Sugar:					
Urea/Creat:		Na+		K+		Cl					
LFT:	TB:		DB:		AST:		ALT:		GGT:		
	SAP:		TP:		Alb:		Glo:				
CA 19-9		HBsAg:				Anti-HCV:					
CXR:				ECG:							

OGD:

USG:

CECT/MRI:

Intraoperative Parameters:

GJ: Antecolic / Retrocolic Associated vascular resection: Yes / No

Operative time: min Blood loss: ml

Blood transfusion (units): PC: FFP: Platelets:

Intraoperative fluids: ml Intra Op Complications:

Post Operative Recovery / Complications:

I.V. Fluids on the DOS: ml First passed stools on:

POD

RT removed on: POD FJ feeding started on:

POD

Oral Sips started on: POD Solid diet started on:

POD

Shifted to ward on: POD

Drain tubes:

DT Amylase	POD 3	POD 7	POD	Removed on
Right DT				
Left DT				

Complications	Yes / No	Grade (ISGPS)		
Delayed Gastric Emptying		A	B	C
Pancreatic Fistula		A	B	C
Post Operative Haemorrhage		A	B	C

Biliary fistula: Yes / No Intra abdominal collection: Yes / No Wound Infection: Yes / No

Others:

Post operative Intervention:

Histopathological Report:

Tumour size: Grade: Stage: T N M

Lymphovascular invasion: Yes / No

Nodal status:

Margin status:

நோயாளி தகவல் தாள்

கணையம் மற்றும் முன்சிறுகுடல் அறுவை சிகிச்சைக்குப் பின் விரைவு சிகிச்சை முறையின் பாதிப்பு

(Impact of Fast Track rehabilitation protocol following pancreatico duodenectomy)

குறித்த ஆராய்ச்சிக்காக ஒப்புதல் படிவம்

நோயாளிகளுக்கான தகவல்:
ஆராய்ச்சியின் நோக்கமும், ஆதாயங்களும்.

உங்கள் பங்கேற்பு திட்டமிடப்பட்டுள்ள இந்த மருத்துவ ஆராய்ச்சி ஆய்வின் நோக்கம்:

கணையத்தில் ஏற்படும் புற்றுநோய் கட்டிக்கு அறுவைசிகிச்சை மூலம் கணையத்தின் ஒரு பகுதியையும் முன்சிறுகுடலையும் அகற்றிவிடுவதே அதற்கான சரியான மருத்துவ சிகிச்சையாகும். ஆனால் அந்த அறுவை சிகிச்சை பெரிய அறுவை சிகிச்சையாகும்.

பொதுவாக வயிற்றில் செய்யப்படும் பெரிய அறுவை சிகிச்சைக்குப்பின் தாமதமாகவே மூக்கில் மற்றும் விலாவில் உள்ள குழாய்களை எடுப்பது, நோயாளியை நடக்க வைப்பது, மற்றும் உணவு அருந்த செய்வது போன்ற சிகிச்சை முறைகளை மருத்துவர்கள் செய்து வருகின்றனர். ஆனால் கடந்த சில ஆண்டுகளாக பெறுகுடல் அறுவை சிகிச்சைக்கு பின் விரைவு சிகிச்சை முறையை செயல்படுத்தி வருகின்றனர். அவ்வாறு செய்ததன் மூலம் பின் விளைவுகள் மற்றும் மருத்துவமனையில் தங்க வேண்டிய அவகாசம் சற்று குறைவாகவே இருக்கிறது.

அதே போன்ற விரைவு சிகிச்சை முறையை கணையம் மற்றும் முன்சிறுகுடல் அறுவை சிகிச்சைக்குபின் அமல்படுத்துவதன் மூலம் பின்விளைவுகளும் மருத்துவமனையில் தங்கும் அவகாசமும் குறைகிறதா என்று கண்டறிவதே என்னுடைய ஆராய்ச்சியின் நோக்கம் ஆகும்.

உண்டாகக்கூடிய இடர்கள்

கணையத்தில் ஏற்படும் புற்றுநோய் கட்டிக்கு கணையத்தின் ஒரு பகுதியையும் முன் சிறுகுடலையும் அகற்றும் அறுவை சிகிச்சை தான் வழக்கில் உள்ள ஒரே நிரந்தர மருத்துவ சிகிச்சையாகும். இதனால் சில சமயம் பின்விளைவுகள் ஏற்படுவதோடு அறிதாக உயிருக்கு ஆபத்து ஏற்பட வாய்ப்புள்ளது.

ஆனால் அவ்வாறு ஏற்படாதிருக்க அனைத்து சிகிச்சைகளும் மேற்கொள்ளப்படும்

ஆய்வு நடைமுறைகள்

கணைய புற்றுநோய கட்டிக்காக கணையம் மற்றும் முன்சிறுகுடலை அகற்றும் அறுவை சிகிச்சை செய்து கொள்ளும் நோயாளிகள் மட்டுமே இந்த ஆய்வில் சேர்த்து கொள்ளப்படுவார்கள். இந்த ஆராய்ச்சி 10 மாதங்கள் நடைபெறும். உங்கள் சிகிச்சைக்கு தேவையானது தவிர வேறு எந்த பரிசோதனையோ செய்முறை பயிற்சிகளோ செய்யப்படாது என்று உறுதி அளிக்கிறேன்.

அந்தரங்கத்தன்மை

உங்கள் மருத்துவப் பதிவேடுகள் மிகவும் அந்தரங்கமாக வைத்துக் கொள்ளப்படும் மற்றும் மற்ற பிற மருத்துவர்கள் / விஞ்ஞானிகள் / இந்த ஆய்வின் தணிக்கையாளர்கள் அல்லது ஆராய்ச்சி ஆதரவாளர்களின் பிரதிநிதிகள் ஆகியோரிடமும் அவை வெளிப்படுத்தப்படும். இந்த ஆய்வின் முடிவுகள் அறிவியல் பத்திரிக்கைகளில் பிரசுரிக்கப்படலாம். ஆனால், பெயரை வெளியிடுவது மூலம் நீங்கள் அடையாளம் காட்டப்பட மாட்டீர்கள்.

ஆய்வில் பங்கேற்கும் நோயாளியின் கடமைப் பொறுப்புகள்

உங்களை கவனித்துக் கொள்ளும் மருத்துவருடன் நீங்கள் முழுமையாக ஒத்துழைக்க வேண்டும் என்று உங்களைக் கேட்டுக்கொள்றோம். சிகிச்சையளிக்கும் மருத்துவர் அளிக்கும் அறிவுரைகளை பின்பற்ற வேண்டும் என்றும், என்னென்ன செய்ய வேண்டும், என்னென்ன செய்யக்கூடாது என்று உங்களிடம் கூறப்பட்டுள்ளவற்றி-ருந்து சற்றும் விலகக்கூடாது என்றும் நீங்கள் எதிர் பார்க்கப்படுகிறீர்கள்.

ஆய்வில் உங்கள் பங்கேற்பு மற்றும் உங்கள் உரிமைகள்

இந்த ஆய்வில் உங்கள் பங்கேற்பு தன்னிச்சையானது மற்றும் காரணங்கள் எதையும் கூறாமலேயே நீங்கள் இந்த ஆய்வி-ருந்து எந்த ஒரு நேரத்திலும் விலகிக் கொள்ளலாம். எப்படியிருந்தாலும், உங்கள் உடல் நிலைக்கேற்ப உங்களுக்கு பொருத்தமான சிகிச்சை அளிக்கப்படும். ஆய்வில் பங்கேற்க நீங்கள் மறுப்பதால், அடுத்து வரும் ஆராய்ச்சி ஆய்வுகளில் உங்கள் பங்கேற்பை மறுப்பது போன்ற எந்தவித அபராதமும் விதிக்கப்படாது. உங்களை கவனித்துக் கொள்ளும் மருத்துவருடன் முழுமையாக ஒத்துழைக்க நீங்கள் சம்மதிக்க வேண்டும். எந்த ஒரு நேரத்திலும், நீங்கள் மோசமாக உணர்ந்தாலோ அல்லது வேறு ஏதேனும் உடல் நலக்குறைவு உண்டானாலோ, தயவு செய்து, உங்களை கவனித்து வரும் மருத்துவரிடம் உடனடியாக தெரிவிக்கவும், சிகிச்சை உங்களுக்குப் பொருத்தமாக இருக்காது என்று தோன்றினால் உடனடியாக நிறுத்தப்படும். உங்கள் சம்மதம் இன்றியே கூட ஆய்வு நிறுத்தப்படுவது சாத்தியமே, ஆய்வின் பொழுது ஏதேனும் புதிய தகவல் தெரிய வந்தால், அதைப்பற்றி உங்கள் மருத்துவர் உங்களுக்கு தெரிவிப்பார்.

வேறு ஏதேனும் கேள்விகள் / பிரச்சனைகள் பற்றி நீங்கள் கேட்க விரும்பினால், கீழ்க்கண்ட நபரைத் தொடர்பு கொள்ளவும்.

தனியாகப் பிரிதெடுத்து, ஆய்வில் பங்கேற்பவரிடம் தரப்பட வேண்டும்.

ஆய்வில் பங்கேற்பவர் / சட்டபூர்வமாக
ஏற்கப்பட்ட நபர் கையொப்பம் அல்லது
தெருவிரல் பதிவு

நோயாளி சம்மத படிவம்

கணையம் மற்றும் முன்சிறுகுடல் அறுவை கிசிச்சைக்குப் பின் விரைவு சிகிச்சை முறையின் பாதிப்பு

(Impact of Fast Track rehabilitation protocol following pancreatico duodenectomy)

குறித்த ஆராய்ச்சிக்காக ஒப்புதல் படிவம்

நோயாளியின் பெயர் .....

வயது ..... வருடங்கள் அல்லது பிறந்த தேதி .....

நோயாளியை தொடர்பு கொள்ளும் முகவரி .....

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நோயாளியின் தொலைபேசி எண்.

நோயாளியின் இன்சியல்ஸ் ..... பா-னம் ஆண் ..... பெண் .....

		பங்கேற்பவரின் இன்சியல்/பெரு விரல் பதிப்பு
1)	மேல் குறிப்பிடப்பட்டுள்ள ஆய்வின் ..... தேதியிட்ட நோயாளிகளுக்கான செய்தி நான் படித்திருக்கிறேன் மற்றும் புரிந்திருக்கிறேன்/ விவரிக்கப்பட்டுள்ளேன். கேள்விகள் கேட்கவும் அனுமதி வழங்கப்பட்டுள்ளேன் என நான் உறுதி செய்கிறேன்.	
2)	இந்த ஆய்வில் பங்கேற்பது என் சொந்த விருப்பப்படியே என நான் புரிகிறேன். மேலும் என் மருத்துவ சிகிச்சை கவனிப்பு அல்லது சட்ட பூர்வ உரிமைகளுக்கு பாதிப்பு ஏற்படாமல் நான் எந்த நேரத்திலும் விலகிக் கொள்ளலாம் என்பதை புரிகிறேன்.	
3)	எத்திக்ஸ் கமிட்டி மற்றும் ரெகுலேட்டரி அதாரிட்டீஸ்க்கும் நான் இந்த ஆய்வி-ருந்து விலகினாலும் தற்போதைய மற்றும் எதிர்கால இந்த ஆய்வு சார்ந்த என் உடல்நல குறிப்புகளை என் அனுமதியின்றி பார்க்க முடியும் என நான் அறிகிறேன்.	
4)	இந்த ஆய்வில் கிடைக்கப்பெறும் குறிப்புகள் மற்றும் முடிவுகளை உபயோகப்படுத்த தடை செய்ய மாட்டேன் என சம்மதிக்கிறேன். ஆனால் அவைகள் விஞ்ஞானம் சம்மந்தப்படடவைகளுக்கு மட்டும் பயன் உள்ளதாக இருக்க வேண்டும்.	
5)	மேற்கூறிய ஆய்வில் பங்கேற்க நான் சம்மதிக்கிறேன்.	

ஆய்வில் பங்கேற்பவர் / சட்டபூர்வமாக
ஏற்கப்பட்ட நபர் கையொப்பம் அல்லது
பெருவிரல் பதிவு

சுய ஒப்புதல் படிவம்

கணையம் மற்றும் முன்சிறுகுடல் அறுவை சிகிச்சைக்குப் பின் விரைவு சிகிச்சை முறையின் பாதிப்பு

(Impact of Fast Track rehabilitation protocol following pancreatico duodenectomy)

குறித்த ஆராய்ச்சிக்காக ஒப்புதல் படிவம்

ஆராய்ச்சி நிலையம் : அரசு ஸ்டான்- மருத்துவமனை
சென்னை - 600 001.

பங்கு பெறும் நோயாளியின் பெயர் : வயது :

பங்கு பெறும் நோயாளியின் எண் : பா-னம் : ஆண் ☐ பெண் ☐

நோயாளியின் விலாசம் :

நோயாளி இதனை (✓) குறிக்கவும்.

மேலே குறிப்பிடப்பட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும். அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது ☐

நான் என்னை இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்க அனுமதிக்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் என்னை இவ்வாய்வில் இருந்து விலக்கி கொள்ளலாம் என்றும் அறிந்து கொண்டேன். ☐

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என் குழந்தையுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். என்னை ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். ☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன். ☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக் கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்த கொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிக்கிறேன். என் உடல் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணிக்கு தெரிவிப்பேன் என உறுதி அளிக்கிறேன். ☐

இந்த ஆய்வில் எனக்கு இரத்தம், சிறுநீர், எக்ஸ்ரே, ஸ்கேன் உட்பட அனைத்து பரிசோதனைகளையும் செய்து கொள்ள நான் முழு மனதுடன் சம்மதிக்கிறேன் ☐

பங்கேற்பவரின் கையொப்பம் ..... இடம் ..... தேதி

கட்டைவிரல் ரேகை (இந்த படிவம் படித்து காட்டப்பட்டு புரிந்து கைரேகை அளிக்கின்றேன்)

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் ..... இடம் ..... தேதி

ஆய்வாளரின் பெயர் .....

MASTER CHART

Master chart – Fast-track group – Page 1.

S. No:	Name	Age	Sex	I.P. No:	Diagnosis	Comorbidities	Hb	Sr. Bilirubin	Sr. Albumin	Duration of surgery (min)	Blood loss (ml)	No. of units transfused	Intraoperative fluids (ml)	RT removed on (POD)	Rt DT removed on (day)	Lt DT removed on (day)
1	Balu	36	M	5514	Duodenal CA	-	12.3	0.85	4	310	425	0	2800	4	8	-
2	Elumalaiyammal	45	F	9136	Periampullary CA	-	11.8	18.9	3.4	295	210	0	3000	4	3	7
3	Lingudurai	62	M	8124	Periampullary CA	-	11.5	13.4	3.5	250	250	0	2500	1	4	-
4	Rajendran	50	M	16533	Periampullary CA	HT	10.1	16.7	3.4	390	230	0	3100	3	4	4
5	Kavitha	30	F	16310	Distal CBD growth	-	12.9	8.2	3.9	420	500	0	1750	1	5	5
6	Sathya priya	15	F	16733	SPN	-	11.6	0.24	4.1	425	350	0	1750	3	6	7
7	Rani	44	F	19312	Periampullary CA	-	12.4	3.41	3.7	360	300	0	1250	4	8	-
8	Nedumaran	60	M	21541	CA Head of Pancreas	-	11.2	13.6	3.6	300	240	0	1500	5	5	7
9	Palaniappan	57	M	20964	Mets from RCC	-	14.4	1.3	4.3	510	750	3	3500	5	5	6
10	Selvi	47	M	22984	Periampullary CA	-	11.4	6.6	3.6	410	375	0	2900	4	7	7
11	Gnana Sundary	45	F	29070	Distal CBD growth	DM, HT	10.1	6.22	4.1	360	330	0	3100	-	-	-
12	Savithri	50	F	27116	Periampullary CA	-	9.9	24.4	3.3	420	750	1	2800	5	5	8
13	Prabavathi	32	F	32179	NET pancreas	-	12.9	0.57	4.1	370	230	0	4000	11	20	20
14	Mubeena	16	F	31353	SPN Head of Pancreas	-	13.7	2.41	4.5	425	250	0	3500	4	5	8
15	Madasamy	59	M	33743	Periampullary CA	-	9.7	0.62	3.8	360	250	0	3100	3	7	8
16	Ramesh babu	40	M	30712	Periampullary CA	-	14.1	17.5	4.3	290	220	0	4000	10	8	10
17	Santha	65	F	35106	CA Head of Pancreas	-	10.2	21.2	3.4	425	300	2	2500	4	16	9
18	Ramayee	62	F	42148	Periampullary CA	-	9	3.1	3	390	290	2	3000	6	4	8
19	Divya	15	F	44705	SPN Head of Pancreas	-	10	0.5	4.4	510	500	1	3200	4	4	6
20	Sampath kumar	54	M	18417	CA Head of pancreas	-	12.7	0.73	3.8	500	400	1	3800	7	7	8

Master chart – Fast-track group – Page 2.

S. No:	Name	Age	Sex	I.P. No:	Liquids started on (POD)	Solids started on (POD)	Passed motion on (POD)	ICU stay (days)	Post OP stay (days)	DGE (Grade)	Pancreatic Fistula (Grade)	PPH (Grade)	Biliary Fistula	Rellaparotomy	Mortality
1	Balu	36	M	5514	4	7	5	4	14	-	A	-	-	-	-
2	Elumalaiyammal	45	F	9136	4	7	5	7	35	-	C	C	Yes	+	Yes
3	Lingudurai	62	M	8124	2	3	3	3	9	-	-	-	-	-	-
4	Rajendran	50	M	16533	3	4	4	4	14	-	-	-	-	-	-
5	Kavitha	30	F	16310	3	4	4	5	9	-	A	-	-	-	-
6	Sathya priya	15	F	16733	3	6	5	6	13	-	A	-	-	-	-
7	Rani	44	F	19312	4	6	5	5	12	-	A	-	-	-	-
8	Nedumaran	60	M	21541	5	8	6	7	13	A	-	A	-	-	-
9	Palaniappan	57	M	20964	6	8	6	6	11	A	-	-	-	-	-
10	Selvi	47	M	22984	4	6	4	6	12	-	A	-	-	-	-
11	Gnana Sundary	45	F	29070	-	-	4	-	6	-	C	C	-	+	Yes
12	Savithri	50	F	27116	7	9	3	8	14	A	A	-	-	-	-
13	Prabavathi	32	F	32179	13	23	5	11	30	C	B	-	Yes	PCD	-
14	Mubeena	16	F	31353	4	7	4	4	12	-	-	-	-	-	-
15	Madasamy	59	M	33743	4	6	6	7	11	-	-	-	-	-	-
16	Ramesh babu	40	M	30712	19	21	4	8	26	C	A	-	-	-	-
17	Santha	65	F	35106	5	6	3	7	44	-	-	C	-	+	-
18	Ramayee	62	F	42148	7	9	4	7	20	B	-	-	-	-	-
19	Divya	15	F	44705	4	6	4	6	14	-	A	-	-	-	-
20	Sampath kumar	54	M	18417	7	9	5	6	14	A	-	-	-	-	-

Master Chart – Control group – Page 1.

S. No:	Name	Age	Sex	I.P. No:	Diagnosis	Comorbidities	Hb	Sr. Bilirubin	Sr. Albumin	Duration of surgery (min)	Blood loss (ml)	No. of units transfused	Intraoperative fluids (ml)	RT removed on (POD)	Rt DT removed on (day)	Lt DT removed on (day)
1	Periasamy	69	M	34294	Periampullary CA	-	10.8	0.83	3.9	480	520	0	3700	8	9	9
2	Chellammal	62	F	34762	Duodenal Carcinoma	HT/IHD	11.4	14	3.5	450	500	0	4800	10	15	17
3	Jayammal	42	F	37097	Periampullary CA	-	10.4	1.25	3.7	480	500	0	3500	6	9	10
4	Ummal Faiseela	48	F	37979	Periampullary CA	-	10.3	1.78	3	360	220	2	2400	8	5	15
5	Arumugam	38	M	39176	Duodenal Carcinoma	-	16.2	0.88	3.9	420	800	0	3500	7	4	7
6	Arivazhagan	35	M	37633	Periampullary CA	-	9.8	3.26	2.7	430	450	2	3500	6	5	6
7	Palani	45	M	39329	Distal CBD CA	DM	14.5	6.13	4	450	300	0	3400	5	7	8
8	Parameshwari	18	F	40225	Duodenal polyp	-	7.9	1	3.9	410	325	3	2500	8	9	11
9	Chandrammal	60	F	41907	Periampullary CA	-	10.6	12.03	3.4	430	400	4	3500	9	8	9
10	Viruthupandiyan	50	M	41543	Distal CBD CA	-	12.1	7.44	4.1	420	200	0	4300	6	12	10
11	Esthar Rani	33	F	43157	Periampullary CA	-	12.4	3.54	3.2	450	350	0	3800	9	5	9
12	Chandraleka	58	F	43711	Carcinoma HOP	-	9.6	0.88	3.6	400	200	0	3500	8	8	8
13	Murugesan	50	M	43824	Distal CBD CA	DM	9.3	18.88	2.7	330	180	0	3000	4	6	8
14	Mariya Louise	55	M	43960	Periampullary CA	DM/HT	13.3	17.3	3.7	570	350	0	3500	4	22	21
15	Raj	55	M	45494	Ampullary CA	-	11.9	11.31	3.7	425	400	1	4500	13	15	16
16	Rani	46	F	45316	Periampullary CA	DM/H	9	1.4	3.6	380	270	1	4200	6	12	16
17	Panchavarnam	42	F	45755	Periampullary CA	DM/H	11.6	1.18	3.7	420	600	0	3500	5	5	8
18	Raghunathan	44	M	44870	Serous Cystadenoma	Anaem	9.3	0.93	4.1	330	600	2	3400	9	9	9
19	Kumari	40	F	2628	Periampullary CA	-	5.7	14.76	3.1	330	500	3	3300	5	5	8
20	Raja	62	M	3129	Duodenal Carcinoma	-	13.8	0.88	3.9	480	400	0	4200	7	7	9

Master chart – Control group – Page 2.

S. No:	Name	Age	Sex	I.P. No:	Liquids started on (POD)	Solids started on (POD)	Passed motion on (POD)	ICU stay (days)	Post OP stay (days)	DGE (Grade)	Pancreatic Fistula (Grade)	PPH (Grade)	Biliary Fistula	Rellaparotomy	Mortality
1	Periasamy	69	M	34294	9	11	5	8	17	A	-	-	-	-	-
2	Chellammal	62	F	34762	10	18	9	22	38	B	-	-	-	SS	-
3	Jayammal	42	F	37097	7	11	5	15	23	A	A	-	-	-	-
4	Ummal Faiseela	48	F	37979	8	10	3	7	19	A	-	-	-	-	-
5	Arumugam	38	M	39176	7	10	7	6	14	A	-	A	-	-	-
6	Arivazhagan	35	M	37633	6	8	4	5	13	A	-	-	-	-	-
7	Palani	45	M	39329	6	9	4	5	36	A	-	C	-	+	-
8	Parameshwari	18	F	40225	9	11	6	6	19	A	A	-	-	-	-
9	Chandrammal	60	F	41907	9	10	6	8	13	A	-	-	-	-	-
10	Viruthupandiyan	50	M	41543	7	10	3	6	14	A	-	-	-	-	-
11	Esthar Rani	33	F	43157	9	14	5	8	28	A	-	-	-	SS	Yes
12	Chandraleka	58	F	43711	9	12	6	7	17	A	A	-	-	-	-
13	Murugesan	50	M	43824	4	7	5	6	15	-	A	-	-	-	-
14	Mariya Louise	55	M	43960	22	25	5	15	29	C	B	-	-	-	-
15	Raj	55	M	45494	13	16	6	8	22	B	A	-	-	-	-
16	Rani	46	F	45316	10	15	6	6	21	B	A	-	-	-	-
17	Panchavarnam	42	F	45755	6	10	5	7	18	A	A	-	-	-	-
18	Raghunathan	44	M	44870	9	15	8	8	21	B	A	-	-	-	-
19	Kumari	40	F	2628	5	9	5	6	16	A	-	-	-	-	-
20	Raja	62	M	3129	8	9	6	5	14	A	A	-	-	-	-